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**PRE-APPEAL BRIEF
REQUEST FOR REVIEW**

Application #	10/622,803
Confirmation #	3480
Filing Date	July 21, 2003
First Inventor	BERTAGNOLI
Art Unit	3733
Examiner	Reimers, Annette R.
Docket #	P07878US00/MP

Applicant requests review of the Final Rejection mailed March 26, 2007 in the above-identified application. No amendments are being filed with this request.

This request is being filed with a NOTICE OF APPEAL.

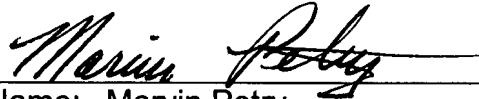
The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the Attorney of Record.

Date: May 17, 2007

By:


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**REMARKS AND ARGUMENTS IN SUPPORT OF
PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Claims 1-14 and 19-35 are pending in the present application, with claims 4, 13, 14, 19-21, 26-28, 31, 32 and 35 withdrawn from consideration. In the final Office Action of March 26, 2007, independent claim 1, its dependent claims 2, 3 and 5-12, and independent claim 22 and its dependent claims 23-25, 29, 30, 33 and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolger et al. (U.S. Patent No. 6,770,096) (hereinafter "Bolger") in view of Martin Benlloch et al. (U.S. Patent No. 6,676,661) (hereinafter "Benlloch"). Applicant respectfully requests that the rejection to the claims be reconsidered in this Pre-Appeal Brief Review and found to be allowable based on the discussion which follows.

In the outstanding rejection, the two independent claims 1 and 22, as well as their respective dependent claims, were rejected by the Examiner, alleging that Bolger discloses all claim elements, except for the claimed retaining structure for securing each of the anchor screws to its respective tube. The Examiner, however, alleges that Benlloch teaches a retaining structure which one of ordinary skill in the art would have found obvious to incorporate with the Bolger device. Specifically, the Examiner alleges that Bolger discloses "exposed threaded ends of the anchoring screws ... each capable of being secured with a retaining structure, i.e., a threaded nut as disclosed in [Martin Benlloch]." (Office Action, March 26, 2007, page 5.)

Contrary to the rejection to the claims based on Bolger in view of Benlloch, the present invention is not obvious from Bolger in view of Benlloch as, absent the present disclosure, one of ordinary skill in the art would have had no reason to combine their individual elements in the manner claimed.

Referring specifically to independent claims 1 and 22, the present invention is directed to a novel and non-obvious instrument for separating at least two vertebrae and/or retaining at least two adjacent vertebrae in a spaced apart condition. Further, referring specifically to claim 1, a plurality of anchors each have a forward end securable to a vertebrae and a rear end remote therefrom. A frame member comprises at least two arms, each arm having a tube, at least in part, encircling one of the anchor screws. Retaining structures secure each of the anchor screws to their respective

tubes. Referring specifically to claim 22, the instrument comprises a plurality of anchor screws, each having a forward end securable to a vertebrae and a frame member comprising at least two arms and a connecting member operatively connecting the two arms for movement toward and away from each other. Each of the arms have an engaging structure operatively associated with one of the anchor screws. Each arm further includes a retaining structure operatively securing the engaging structure of each arm with its respective anchor screw to essentially prevent movement of the anchor screw relative to its engaging structure.

Novelty, in part, of the present instrument over prior instruments lies in a retaining structure which secures each anchor screw to a respective arm of the instrument. Thus, the present instrument attaches securely to the part which the instrument is manipulating. Advantageously, the anchor screws are secured to the instrument so that there is essentially no movement of the anchor screws relative to the insertion tool.

The present retaining structure arrangement is in direct contrast to prior instruments in this art, in which prior instruments are not securely fastened to the part which the instrument is manipulating. Moreover, prior instruments are designed to slidingly engage with a part to allow easy, quick attachment and release and, accordingly, the part is not secured to the instrument. However, unlike conventional instruments, the part manipulated by the instrument is secured to the instrument via the anchor screws. As fully described in the present specification, and in the Remarks section which accompanied the Amendment of March 7, 2006, the retaining structure essentially prevents movement of the anchor screws relative to the frame of the instrument. As a result, the anchor screws maintain their original alignment with the frame and thus prevent any misalignment which might cause the instrument to jam during use (Remarks, March 7, 2006 Amendment, page 1, ¶ 2).

Furthermore, as described in the Remarks of the October 27, 2006 Amendment, the present instrument overcomes a previously undocumented disadvantage in prior art instruments which are not securely fastened to the anchor screws, which become misaligned due to the anchor screws being loosely held in place in a frame of an instrument (Remarks, October 27, 2006 Amendment, page 1, ¶¶ 3-4).

Turning now to the prior art which was the subject of the outstanding rejections to the claims, Bolger is specifically directed to a spinal stabilization cage which is disposed between two adjacent vertebrae and is anchored to allow no degree of freedom (see, e.g., Bolger, column 2, lines 35-45 and column 4, lines 18-46, and the Remarks to the October 27, 2006 Amendment, page 3, paragraph 1-page 5, first full paragraph). As with similar prior art instruments, the Bolger instrument slidably engages with rods inserted into adjacent vertebrae to allow their separation during insertion of the anchor means, and, after the anchor means is attached, to slidably remove the instrument.

Benlloch discloses a connecting rod (1) with threaded ends for permanently attaching a connecting element (4) to a vertebrae. (Benlloch, Figures 1-3 and column 2, line 44-column 3, line 3.) Benlloch is specifically directed to affixing a permanent spinal implant in a patient using a nut (9) which is tightened down on the threaded end of rod (1), which has been inserted into a vertebrae through bore (10) (Benlloch, Figure 1). Thus, the Benlloch disclosure is limited to a spinal implant. Benlloch fails to disclose any insertion tool or instrument for inserting the tool or connector in a patient. Furthermore, the disclosure of Benlloch is limited to permanently securing an implant in place on the spinal column of a patient.

Contrary to the Examiner's allegation, it would not have been obvious to one of ordinary skill in the art to arrive at the present instrument for separating at least two adjacent vertebrae comprises a plurality of anchors and a frame member comprising at least two arms secured to the anchor screws using a retaining structure, as recited in independent claims 1 and 22 from Bolger in view of Benlloch. Specifically, one of ordinary skill in the art would not have combined the insertion instrument of Bolger with the connecting rod of Benlloch, as there fails to be any reason why one of ordinary skill in the art would have combined the individual elements of the instrument of Bolger and the retaining structure of the Benlloch connecting rod in the manner claimed.

To establish a *prima facie* case of obviousness, there must be more than a demonstrated evidence of all components of the claimed subject matter present in one or more prior art references. There must be some reason for the combination whereby a person of ordinary skill in the prior art would make the substitutions or modifications required in the present invention. The reason for the combination can be in the form of

a recognized problem in the art which the combination solves. (See *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____ (2007). However, the knowledge of a recognized problem or reason for the combination cannot come from the Applicant's disclosure of the invention itself. (See, *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 678-79, 7 USPQ2d 1315, 1318 (Fed. Cir. 1988); *In re Geiger*, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985), *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992)).

Although Bolger depicts, in Figures 11-13, exposed thread ends of its rods, one of ordinary skill in the art would not have considered using any retaining structure to secure the threaded ends of the bolts to the frame of its instrument. An insertion tool arrangement of securing a manipulating instrument to the part to be manipulated would be contrary to what one of ordinary skill in the art would consider such an insertion tool arrangement to be. Such a secured arrangement would prevent one from using the tool in a conventional manner, i.e. slipping the tool onto the ends of the anchor screws, separating adjacent vertebrae, and then sliding the tool off of the anchor screws.

Moreover, the cited prior art, including Bolger, is completely silent with regard to any rationale or acknowledgment of any reason why one would wish to temporarily securely fasten the rods to the frame of the instrument. Accordingly, the cited prior art fails to appreciate any problem with the engagement of the anchor screws with their instrument(s), fails to identify any problem associated with the engagement of the anchor screws with their instrument(s) and, therefore, fails to provide any reason for one of ordinary skill in the art to modify its instrument to include a retaining structure for securing the anchor screws to their instrument(s).

Further, Benlloch fails to provide any reason for one of ordinary skill in the art to use its retaining structures for temporarily attaching an implant to an insertion instrument during insertion and implantation. As acknowledged in the specification, and as is ubiquitous in the present art as evidenced by Bolger, the presence of threadings on anchor bolts, connecting rods and the like, and the use of nuts to attach thereto, does not in any way provide any reason for one of ordinary skill in the art to use such attachment means to temporarily secure an implant to an insertion instrument. The

prior art fails to provide any reason for one of ordinary skill in the art to make such a modification. It is only through an identification of there being a problem with prior instruments, and, in particular, the loose engagement of the instrument with the anchor screws as disclosed in the present specification, that one of ordinary skill in the art would have any reason to securely fasten the anchor screws to the frame of an insertion instrument.

For a more complete discussion, see the Remarks to the October 27, 2006 Amendment, pages 3-5.

Based on the foregoing, Applicant respectfully submits that the prior art of Bolger in view of Benlloch fails to make obvious the claimed instrument of independent claims 1 and 22. In addition, Applicant respectfully submits that dependent claims 2, 3, 5-12, 23-25, 29, 30, 33 and 34, which depend from either independent claim 1 or independent claim 22, are not obvious for at least the same reasons as independent claims 1 and 22, and further for including additional elements not taught or suggested in the prior art.

In view of the foregoing, Applicant respectfully requests that the prior rejections be reconsidered and all claims found allowable over the prior art.

END REMARKS